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10/695,471	10/28/2003	Janaswamy Madhusudana Rao	0640/71348/JPW/AG	5608

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/695,471

Applicant(s)

RAO ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7 and 9-12 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/3/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on October 24, 2006 with Applicant's cancellation of Claim 53.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7 and 9-12 are under examination.

Specification

Again, Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, Applicant should avoid the use of the phrase "The present invention", which appears in line 1 of the abstract.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 7 and 9-12 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language "A herbal composition for the treatment of gastric ulcer, said composition comprising of powdered plant parts selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*, *Cyclea peleta*, *Embelia ribes*, *Coriandum sativum*, *Ferula asafetida*, *Aloe barbadensis* and *Evolvulus alsionoides* and one or more pharmaceutically acceptable additives or carriers wherein said composition essentially comprises *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions" in Claim 1. Newly applied as necessitated by amendment.

The claims as set forth in the amendment filed on October 24, 2006 now recite a herbal composition for the treatment of gastric ulcer comprising powdered plant parts of a single constituent selected from claim-designated members of a recited Markush group characterized by divergently different botanicals. Given that the phrase "wherein said composition essentially comprises *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about

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equal proportions" in Claim 1 fails to particularly set forth the metes and bounds of the meaning of this claim limitation, Claim 1 as presently drafted can be construed as reading on a composition merely comprising only one of the claim-designated members recited in the Markush group therein. However, the specification as originally filed provides only for compositions comprising powdered plant parts of at least five disclosed botanicals, namely *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions, wherein the equal proportions of the botanicals comprising the composition has a value that is greater than zero. Thus, the original concept of the invention has been broadened to encompass compositions comprising a single powdered plant of the botanical constituents recited in the Markush group of Claim 1. It is clear from the specification that Applicant intended to **include and not exclude compositions comprising each of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions, wherein the equal proportions of the botanicals comprising the composition has a value that is greater than zero.**

Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genera which would show possession of the concepts for a herbal composition for the treatment of gastric ulcer, said composition comprising of powdered plant parts selected from the group consisting of *Asparagus*

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racemosus, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*, *Cyclea peltata*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafetida*, *Aloe barbadensis* and *Evolvulus alsionoides* and one or more pharmaceutically acceptable additives or carriers wherein said composition essentially comprises *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions, with regard to Claim 1. There is only one exemplified composition comprising powdered plant parts of at least five of the claim-designated botanicals recited in the Markush group recited in Claim 1, namely *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. This is not sufficient support for the new aforementioned genera/genus. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitation is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitation could not be found in the present specification, the recitation of the claim limitations is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

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While Applicant may argue that the phrase "wherein said composition essentially comprises *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions" further defines the scope of the instantly claimed invention, the Office notes that the substantial amendment to Claim 1 fails to fully and particularly define the instantly claimed invention for reasons clearly set forth immediately below 35 U.S.C. 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 9-12 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 1 are rendered vague and indefinite by the phrase, "wherein said composition essentially comprises *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions", because the subject matter of the preamble is directed to a composition comprising powdered plants selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*, *Cyclea peltata*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafetida*, *Aloe barbadensis* and *Evolvulus alsionoides* and one or more pharmaceutically acceptable additives or carriers. It is unclear as to how the instantly claimed composition can "essentially comprise[s] *Asparagus racemosus*,

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Glycyrrhiza glabra, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions”, when the scope of the preamble encompasses subject matter to compositions that can comprise powdered plants of a single botanical selected from a Markush group consisting of eleven claim-designated members, which recites powdered plants of botanicals other than the five botanicals recited in the aforementioned phrase.

Moreover, the claim language of the phrase, “wherein said composition essentially comprises *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions”, is not set forth in terms of a weight, volume, percentage, or ratio having a value greater than zero. Therefore, Claim 1 as presently drafted does not necessarily require the presence of any of or all of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*, if the value of the equal proportions of the aforementioned botanicals is set at a value or 0, for example. Given the foregoing, as presently amended, Claim can be interpreted as reading on a composition merely comprising a single powdered plant part[s] selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*, *Cyclea peltata*, *Embelia ribes*, *Coriandum sativum*, *Ferula asafetida*, *Aloe barbadensis* and *Evolvulus alsinoides*, and one or more pharmaceutically acceptable additives or carriers. The lack of clarity renders the claim very vague and ambiguous.

Please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: *In re Steele*, 305 F.2d. 859, 134 USPQ 292 (CCPA 1962); *In re Moore* 439 F.2d. 1232, 169 USPQ 236 (CCPA 1969); *In re Merat*, 519 F.2d. 1390, 186 USPQ 471 (CCPA 1975).

Contrary to Applicant's arguments that the amendment to Claim 1 obviates the rejection set forth in the previous Office action with regard to metes and bounds of the phrase "said composition essentially comprising" as being vague and indefinite, the metes and bounds of Claim 1 at lines 9 to 10 remain vague and indefinite by the aforementioned phrase because it is unclear as to what subject matter encompasses the meaning of the phrase "essentially comprising". For instance, does Applicant intend to direct the subject matter of the claimed invention to a composition comprising one ingredient or to a composition comprising five ingredients, namely *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* to the exclusion of the other additional claim-designated botanicals recited in the Markush group of Claim 1.

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Claims 1-7 recite the terms: "*Evolvulus aidinodes*", "*Trachyparmum roxburghicinum*", and "*Cyclea peleta*". However, a thorough search of both patent and non-patent literature found no evidence that any of the claim-designated plants occur in nature. Thus, the claims are unsearchable as no genus-species with the prescribed names were found searchable. It appears that the terms are misspellings of botanicals, which appear misspelled in the claims, as well as in the specification. Appropriate correction is required, if the assumption is true. If not, the Examiner's preliminary analysis and search demonstrates that the claimed subject matter cannot be adequately searched by class or keyword among patents and typical sources of non-patent literature.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hong-Yue (A*), Dehpour et al. (V) and Christina et al. (V1). Newly applied as necessitated by amendment.

As discussed above in the rejection made under 35 U.S.C. 112,-second paragraph, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, for the purpose of expeditious prosecution and examination of the instantly claimed invention on the merits a search was conducted for what reasonably appears to be Applicant's claimed invention. For all of the reasons set forth above in the rejections of the claims made under 35 U.S.C. 112, first and second paragraphs, the claims have been construed as reading on a herbal composition for the treatment of gastric ulcer comprising powdered plant parts selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*, *Cyclea peleta*, *Embelia ribes*, *Coriandum sativum*, *Ferula asafetida*, *Aloe barbadensis*

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and *Evolvulus alsinoides*, and one or more pharmaceutically acceptable additives or carriers.

Hong-Yue teaches an antipeptic ulcer comprising powdered liquorice and clove (read herein as a pharmaceutically acceptable additive or carrier.).

Dehpour teaches a composition comprising powdered root of *Glycyrrhiza glabra* that is used to coat ibuprofen (read herein as a pharmaceutically acceptable additive or carrier), which is used to treat gastric lesions.

Christina teaches a composition comprising root powder of *Cyclea peltata* and milk (read herein as a pharmaceutically acceptable additive or carrier.). It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

The references anticipate the claimed invention.

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Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida (N). Newly applied as necessitated by amendment.

Yoshida teaches a composition comprising a powdered seed oil extract of *Sesamum indicum* that is beneficial in the treatment for peptic ulcers.

The reference anticipates the claimed subject matter.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al. (W1).

Lewis teaches a composition comprising unripe fruit powder of *Musa sapientum* and food (read herein as a pharmaceutically acceptable additive or carrier) having anti-ulcerogenic properties, on page 285, Column 1, under "2.6. Acid stability".

The reference anticipates the claimed subject matter.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Goel et al. (X). Newly applied as necessitated by amendment.

Goel teaches a herbal composition for the treatment of gastric ulcer comprising fruit powder of *Musa sapientum* and water (read herein as a pharmaceutically acceptable additive or carrier), on page 34, third paragraph.

The reference anticipates the claimed subject matter.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Rao et al. (X1), and Singh et al. (U2). Newly applied as necessitated by amendment.

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Rao teaches a composition comprising a fruit powder of *Embelia ribes* and a plant oil (read herein as pharmaceutically acceptable additive or carrier).

Singh teaches a fruit powder of *Embelia ribes* and other plant extracts (read herein as pharmaceutically acceptable additive or carrier).

It is noted that neither Rao nor Singh teaches that either of the compositions can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art compositions. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sakakibara et al. (B*). Newly applied as necessitated by amendment.

Sakakibara teaches a composition comprising powdered plant parts of *Coriandum sativum* and a food product (read herein as a pharmaceutically acceptable additive or carrier), in Column 3, lines 7-61. It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the

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intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

The reference anticipates the claimed subject matter.

Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Haney (C*) and Hankey (W2), as evidenced by the teachings of Remington et al. (U). Newly applied as necessitated by amendment.

Haney teaches a composition comprising powdered *Ferula asafetida* in combination with a mixture comprising salt, a mixture of powdered mustards, sugar, powdered tumeric, powdered milk and powdered dextrin (read herein as a pharmaceutically acceptable additive or carrier), in Column 1, lines 48-61.

Hankey teaches a composition comprising powdered *Ferula asafetida* in alcohol (read herein as a pharmaceutically acceptable additive or carrier).

It is noted that neither Haney nor Hankey expressly teach that the reference composition is a powdered plant part of *Ferula asafetida* resin. However, Johnson

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teaches that powder asafetida is prepared from resin obtained from the roots and rhizomes of the plant. Therefore, absent evidence to the contrary, the reference compositions are deemed powdered resin of *Ferula asafetida*.

It is noted that the references do not teach that the compositions can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art compositions. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

The reference anticipates the claimed subject matter.

Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Palpu et al. (D*). Newly applied as necessitated by amendment.

Palpu teaches a herbal composition for the treatment of gastric ulcer comprising powdered tuber of *Asparagus racemosus* and other powdered plant parts of other plants (read herein as a pharmaceutically acceptable additive or carrier). See patent claims.

The reference anticipates the claimed subject matter.

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Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by McAnalley (E*).

McAnalley teaches a composition for the treatment of gastric ulcer comprising powdered *Aloe vera* (also known in the art of botany as *Aloe barbadensis*), in Column 29, lines 35-43. In Column 30, lines 34-67, McAnalley teaches a powdered *Aloe vera* in a phosphate buffer (read herein as a pharmaceutically acceptable additive or carrier).

The reference anticipates the claimed subject matter.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Purohit et al. (X2). Newly applied as necessitated by amendment.

Purohit teaches a herbal composition for the treatment of gastric ulcer comprising fruit powder of *Evolvulus alsinoides* in an alcohol solvent buffer (read herein as a pharmaceutically acceptable additive or carrier).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 1, 2 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palpu (D*), Hong-Yue (A*), Dehpour (V), Yoshida et al. (N), Lewis et al. (W1) and Johnson (W). Newly applied as necessitated by amendment.

As discussed above in the rejections made under 35 U.S.C. 112, first and second paragraphs, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention. Herein the claims have been construed as reading on a composition essentially comprising *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions, and one or more pharmaceutically acceptable additives or carriers.

Applicant claims a herbal composition for the treatment of gastric ulcer, said composition comprising of powdered plant parts selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*, *Cyclea peleta*, *Embelia ribes*, *Coriandum sativum*, *Ferula asafetida*, *Aloe barbadensis* and *Evolvulus alsinoides* and one or more pharmaceutically acceptable additives or carriers wherein said composition essentially comprises *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions.

Firstly, Palpu teaches a herbal composition for the treatment of gastric ulcer comprising powdered tuber of *Asparagus racemosus* and other powdered plant parts of

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other plants (read herein as a pharmaceutically acceptable additive or carrier). See patent claims. Secondly, Hong-Yue teaches an antipeptic ulcer comprising powdered liquorice and clove (read herein as a pharmaceutically acceptable additive or carrier.); and, Dehpour teaches a composition comprising root powder of *Glycyrrhiza glabra* that is used to coat ibuprofen (read herein as a pharmaceutically acceptable additive or carrier), which is used to treat gastric lesions. Thirdly, Yoshida teaches a composition comprising a powdered seed oil extract of *Sesamum indicum* that is beneficial in the treatment for peptic ulcers. Fourthly, Lewis teaches a composition comprising unripe fruit powder of *Musa sapientum* and food (read herein as a pharmaceutically acceptable additive or carrier) having anti-ulcerogenic properties, on page 285, Column 1, under "2.6. Acid stability". Fifthly, Johnson teaches *Trachyspermum roxburghianum* as having functional effect in the treatment of dyspepsia.

The teachings of Palpur, Hong-Yue, Dehpour, Yoshida, Lewis and Johnson are set forth above. The prior art does not teach a composition comprising each of the instantly claimed ingredients. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art; and one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claim-designated ingredients in the making of the instantly claimed composition because at the time the invention was made each of the powdered plant parts of *Asparagus racemosus* tuber, *Glycyrrhiza glabra* root, *Sesamum indicum* seed, unripe fruit of *Musa sapientum* and *Trachyspermum roxburghianum* were known in the art of herbal medicine to be useful for the treatment of treating gastric ulcer. Thus, at the

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time the invention was made, one of ordinary skill in the art would have been motivated, and one would have had a reasonable expectation of success to combine the powdered plant parts taught by Palpu, Hong-Yue, Dehpour, Yoshida, Lewis and Johnson to provide the instantly claimed invention because the prior art references teach that powdered plants of the claim-designated exert the beneficial functional effect of anti-ulcer activity.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations, as well as the experimental parameters for the manufacturing thereof, are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

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Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1, 2 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palpur (D*), Hong Yue (A*), Dehpour (V), Yoshida et al. (N), Lewis et al. (W1) and Johnson (W) in view of Khrenova et al. (U1), McAnalley (E*), Yang (O) and Purohit et al. (X2). Newly applied as necessitated by amendment.

As discussed above in the rejections made under 35 U.S.C. 112, first and second paragraphs, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention. Herein the claims have been construed as reading on a composition essentially comprising *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions.

The combined teachings of Palpur, Hong Yue, Dehpour, Yoshida, Lewis and Johnson, as set forth immediately above, teach a composition for the treatment of gastric acid essentially comprising *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions, and one or more pharmaceutically acceptable additives or carriers. The combined teachings of Palpur, Hong Yue, Dehpour, Yoshida, Lewis and Johnson teach the instantly claimed invention except for wherein the composition comprises

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powdered plant parts of *Coriandrum sativum*, *Aloe barbadensis*, *Ferula asafetida*, and *Evolvulus alsinoides*. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the composition taught by the combined teachings of Palpur, Hong Yue, Dehpour, Yoshida, Lewis and Johnson to provide the instantly claimed invention because Khrenova, McAnalley, Yang and Purohit taught that the beneficial functional effect of each of the claim-designated ingredients. For example, Firstly, Khrenova teaches a herbal composition for the treatment of gastric ulcer comprising a fruit extract of *Coriandrum sativum*. Secondly, McAnalley teaches a composition for the treatment of gastric ulcer comprising powdered *Aloe vera* (also known in the art of botany as *Aloe barbadensis*), in Column 29, lines 35-43. In Column 30, lines 34-67, McAnalley teaches a powdered *Aloe vera* in a phosphate buffer (read herein as a pharmaceutically acceptable additive or carrier). Thirdly, Yang teaches a herbal composition for the treatment of gastric ulcer comprising asafetida (also known in the art of botany as *Ferula asafetida*). Lastly, Purohit teaches a herbal composition for the treatment of gastric ulcer comprising fruit powder of *Evolvulus alsinoides*. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation to add any of the claim-designated ingredients of powdered plant parts of *Coriandrum sativum* fruit, *Aloe barbadensis*, *Ferula asafetida* and *Evolvulus alsinoides* to the composition taught by the combined teachings of Palpur, Hong Yue, Dehpour, Yoshida, Lewis and Johnson to provide the instantly claimed invention because each of the claim designated ingredients were in

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the art of herbal medicine as being useful in the treatment of gastric ulcer, as by the prior art teachings.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations, as well as the experimental parameters for the manufacturing thereof, are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khrenova et al. (U1). Newly applied as necessitated by amendment.

As discussed above in the rejection made under 35 U.S.C. 112,-second paragraph, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention.

Applicant claims a composition for the treatment of gastric ulcer comprising powdered fruit plant parts of *Coriandrum sativum* and one or more pharmaceutically acceptable additives or carriers.

Khrenova teaches a herbal composition for the treatment of gastric ulcer comprising a fruit extract of *Coriandrum sativum*.

The teachings of Khrenova are set forth above. It is not clear from the teachings of Khrenova whether the reference composition is in the form of a powder and comprising one or more pharmaceutically acceptable additives or carriers. However, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill would have been motivated and would have had a reasonable expectation of success to provide the composition taught by Khrenova in the form of a powder comprising one or more pharmaceutically acceptable additives or carriers because at the time the invention was made it was well known in the art of pharmacy to powder drugs having beneficial functional effects in the treatment of gastric ulcers and to add one or more pharmaceutically acceptable additives or carriers thereto to provide a composition for the delivery of the product to patients in need thereof, for the purpose of storage and for

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the purpose of commercial sale, as evidence by the teachings of the prior art references referred to herein and because Khrenova teaches that fruit extract of *Coriandrum sativum* contain phytochemicals having anti-ulcerous activity.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao et al. (V2). Newly applied as necessitated by amendment.

As discussed above in the rejection made under 35 U.S.C. 112, second paragraph, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention.

Applicant claims a composition for the treatment of gastric ulcer comprising powdered fruit plant parts of *Trachyspermum roxburghianum* and one or more pharmaceutically acceptable additives or carriers.

Rao teaches a herbal composition for the treatment of gastric ulcer comprising fruit powder of *Carum roxburghianum* (also known in the art of botany as *Trachyspermum roxburghianum*), on page 16, Column 2, under "Powder".

The teachings of Rao are set forth above. Rao teaches the instantly claimed invention except for wherein the composition comprises one or more pharmaceutically acceptable additives or carriers. However, it would have been obvious to one of

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ordinary skill in the art to add the claim-designated ingredients to the fruit powder botanical taught by Rao to provide the instantly claimed composition because at the time the invention was made it was well known in the art of pharmacy to add one or more pharmaceutically acceptable additives or carriers to a drug known to serve as a vehicle for a botanical drug known to have beneficial health promoting effects, and for purposes of storage and for the commercial sale of a drug product. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claim-designated ingredients to the fruit powder taught by Rao to provide the instantly claimed invention because Rao teaches that the fruit of *Trachyspermum roxburghianum* is known in the art of traditional medicine as being useful in the treatment of hiccough, vomiting, and pain in the stomach.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Purohit et al. (X2). Newly applied as necessitated by amendment.

As discussed above in the rejection made under 35 U.S.C. 112, second paragraph, Applicant's claims are indefinite to the point where a proper search among patent and non-patent literature is almost precluded. However, a search was conducted for what reasonably appears to be Applicant's claimed invention.

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Applicant claims a composition for the treatment of gastric ulcer comprising powdered plant parts of *Evolvulus alsinoides*, and one or more pharmaceutically acceptable additives or carriers.

Purohit teaches a herbal composition for the treatment of gastric ulcer comprising an alcohol extract of fruit powder of *Evolvulus alsinoides*.

The teachings of Purohit are set forth above. The alcohol extract taught by Purohit is not in the form of a powder and does not contain one or more the claim designated additive or carriers. However, it would have been obvious to one of ordinary skill in the art to provide the reference taught by Purohit in the form of a powder and to add the claim-designated ingredients to the composition taught by Purohit to provide the instantly claimed composition because at the time the invention was made it was well known in the art of herbal medicine to dry alcohol extracts of herbal ingredients having beneficial health promoting effects into a powder form and to add one or more pharmaceutically acceptable additives or carriers to the powder as a vehicle for the delivery of the drug to consumers, and for purposes of storage and for the commercial sale of a drug product. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to formulate the extract taught by Purohit as a powder and to add the claim-designated ingredients to the powdered extract to provide the instantly claimed invention because Purohit teaches that extract of *Evolvulus alsinoides* demonstrated marked antiulcer activity *in vivo*.

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Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Allowable Subject Matter

Claim 5 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: Nowhere in the prior art is there a disclosure teaching or suggesting that *Cyclea peltata* is useful in the treatment of gastric ulcer.

No claims are allowed.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
January 18, 2007